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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/950,963	10/15/1997	JOEL A. DREWES	074022-3302	9997

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EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

29

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/950,963

Applicant(s)

Drewes et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 12, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above, claim(s) 13-17 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 18-34, and 36-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 27
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Applicants' arguments, filed 2/12/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

PRIORITY

If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. It is noted that this appears as the second sentence of the specification following the title, as a separate paragraph. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. No status for application serial number 08/742,255 is shown in said second sentence of the instant specification.

TITLE

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which

the claims are directed. The present title includes broad, generic, methods and devices but such generic methods are not presently under examination. In contrast only laminar flow providing, or diamond-like carbon attachment layered, devices are claimed as well as only methods for the construction of such devices. Applicants have suggested a new title which does adequately summarize the claimed invention, except for yet lacking a phrase directed to the methods of construction thereof claims.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 9, 18-20, 22-24, 26, and 36 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Brecht et al. [Anal. Chim. Acta. 311:289(1995)].

This rejection is reiterated and maintained from the previous office action, mailed 5/6/02. Applicants argue that the Brecht et al. reference does not describe laminar flow and alleges that previously supplied evidence has not been responded

to as being insufficient. Applicants have not pointed specifically to what evidence is meant by this argument. However, in order to fully respond a review of the lengthy prosecution history has been performed to find such evidence. Paper No. 10, filed 2/7/00, may be what applicants intend to summarize such evidence. This evidence points to page 296 of Brecht et al. as describing flow irregularities and describes no increase in analytical performance using the "laminar flow" cell. Consideration of this page 296 citation reveals that Figures 7 and 8 are being discussed wherein Figure 7 clearly is data from a laminar flow cell study. This data is compared to the wall jet flowcell which exhibits said turbulent or irregular flow and has a different data output set of results. This pointing to this wall jet flow cell does not negate the clear description of a laminar flow cell study and thus this argument is non-persuasive as it is a moot argument to point to a flow cell type which is not the basis for this rejection. Applicants then argue that the calculated flow rate of 133 flow cell volumes/min is a high flow rate and point to a reference stating that high fluid velocities are associated with turbulent flow. In response the flow cell volumes/min is not a fluid velocity and thus such a value cannot be reasonably compared to a reference citation. Also, Brecht et al. clearly cites laminar flow at various citations therein including in the legend of Figure 7 and thus discloses such flow

as required in the instant claims. Applicants then argue that the Brecht et al. flow is not "through" the layers of the device. In response applicants are pointed to their own specification at page 11, lines 3-6, where applicants utilize their lexicography as filed to include flow through layers as well as across the surface of any layer in the phrase "through the layers of the device". It is noted that applicants have attempted to amend the claims to clarify this flow "through" issue but that definitions in the specification such as at page 11 as cited still result in the Brecht et al. device practice being included as there is no negation of the page 11 broad and inclusive flow description in the claims.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 2, 5, 6, 9, 18-20, 22-24, 26, and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Oberhardt (P/N 4,849,340).

This rejection is reiterated and maintained from the previous office action, mailed 12/26/02. Applicants firstly argue that the specification at page 10, lines 4-23, distinguishes the Oberhardt optical signal producing device limitations of labeled species such as fluorescent molecules from that of the instant invention. In response, page 10, lines 4-6, clearly describe a broadly defined "optically functional layer" as one which can produce a signal upon binding of analyte to a receptive layer. This is a broad generic definition which clearly is inclusive of any layer that produces a signal whether the signal is produced via fluorescent molecules or by other means. Consideration of the remainder of this citation on page 10 reveals that the layer is characterized via examples of layer contents but without any negative limitations that exclude the Oberhardt optical signaling device characteristics. Thus, the broad generic definition of what is meant by the instantly claimed "optically functional layer" is inclusive of the Oberhardt layer type(s) and thus this argument is non-persuasive. Applicants then argue that the file history may be utilized to

limit the meaning of words and cite the legal decision of *Vitronics Corp. v. Conceptronic Inc.* Consideration of this legal decision reveals that there is therein no support for applicants' adding of new limitations via the file history, but that rather only in helping to determine the interpretation of claims. Thus, this argument still is non-persuasive also described in the previous office action, mailed 12/26/02. Applicants then argue that the claims have been amended to require that a change in mass alters an optical property. In response the claim limitations lack any limitation as to what aspect of this mass change results in the change in optical property. Thus, the signaling moieties of Oberhardt are still deemed mass changes due to such moieties having mass as chemical entities and also change the optical properties via signaling moiety characteristics. Applicants then argue that the reference does not describe laminar flow in the use of the device. In response, a device is being claimed and not a method of use. As such the flow therethrough relates to how fast the flow is and may be fast or slow through any device as in Oberhardt, or, even stop at times. Thus, the use regarding laminar flow or any other type of flow or non-flow is irrelevant as any device may support laminar flow if desired with slow flow rates.

Claims 1-7, 18, 19, 21, 23, 25, 36, and 38-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Walt et

al. (P/N 6,023,540).

This rejection is reiterated and maintained from the previous office action, mailed 12/26/02. Applicants argue that priority to the parent application; serial number 08/742,255; predates the Walt et al. reference. In response, the instant application is a continuation-in-part from said parent 08/742,255. Applicants point to various citations in the parent serial number 08/742,255 so as to support the allegation of priority thereto. Consideration of the support for the amendments to the instant claims directed specifically to providing channels through "each" of the optically functional layer, attachment layer, and analyte receptive layer in said parent lacks written basis in said parent. In the parent specification at page 5, line 28, through page 6, line 2, only the optical functional layer is described as containing a "channel". The citation to page 31, lines 16-17, is directed to vapor deposition and lacks channel description. The citation to page 13, lines 5-13, also only cites a channel(s) in the optically functional layer with a porous support and also fails to provide basis for priority for the instant claims which require a channel through all three layers given as 1) optically functional layer, 2) attachment layer, and 3) analyte receptive layer. In summary, therefore this argument is non-persuasive and priority is not granted to said parent application.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5-12, 23, 24, 26-34, and 36-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51, 52, 54, 55, 57-63, 66-68, 70, 71, 73-79, and 82 of copending application Serial No. 09/675,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because the supports claimed in said copending application are not merely supports but also contain layers as instantly claimed. For example, claim 54 of 09/675,518 requires an antireflective layer of diamond-like carbon as well as the support and attachment layer of claim 51 due to its dependence from claim 51. These are embodiments within instant

claim 39. Such combinations of limitations are therefore also present in independent claims due to dependent claims therefrom. It is noted that the particle limitations of certain instant claims, however, are not present in the claims as listed above from the copending application. No argument has been directed specifically to this rejection which is therefore maintained from the previous office action due to the non-allowability of the instant claims.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application contains claims 13-17 and 35 drawn to an invention non-elected with traverse in Paper No. 6, filed 6/28/99. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action

(37 C.F.R. § 1.144) M.P.E.P. § 821.01.

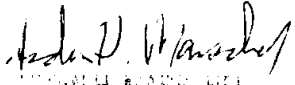
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 20, 2003


ARDIN H. MARSCHEL
Legal Instrument Examiner